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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,341	06/09/2006	Kazuyoshi Gamada	135-03	5446

23713 7590 01/25/2008
GREENLEE WINNER AND SULLIVAN P C
4875 PEARL EAST CIRCLE
SUITE 200
BOULDER, CO 80301

EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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01/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/596,341

Applicant(s)

GAMADA, KAZUYOSHI

Examiner

Kim M. Lewis

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-12, 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 13 and 18 is/are rejected.
- 7) ☐ Claim(s) 15-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Detailed Action.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 10/22/07 has been received and made of record. As requested, claims 14 has been cancelled and claims 13 and 15 have been amended.
2. Claims 1-13 and 15-20 are pending in the instant application.

Allowable Subject Matter

3. The indicated allowability of claim 14, the subject matter of which has been added to claim 13, is withdrawn in view of the newly discovered reference(s) to Turrini et al. and *KSR Int'l Co. v. Teleflex, Inc.* rationale. Rejections based on the newly cited reference(s) and the *KSR Int'l Co. v. Teleflex, Inc.* rationale follow.
4. Claims 1-12, 19 and 20 are allowed.
5. Claims 15-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterling in view of U.S. Patent Application Publication No. 2005/0159691 A1 ("Turrini et al.").

As regards claim 13, Sterling discloses an anatomically designed orthopedic knee brace that inherently anticipates applicant's presently claimed invention. More specifically, Sterling discloses a method for treating a knee pathology comprising, altering an abnormal rotation of the tibia, wherein said altering involves applying a rotational force to the tibia during flexion in a direction opposite to that of said abnormal rotation, and applying an off-loading force to the knee, wherein said rotational force and said off-loading force is applied repeatedly during every flexion/extension.

Sterling discloses in para. 0027, that when the brace employs a medial hinge, it functions to relieve unicompartmental osteoarthritis affecting the medial condyle and when the lateral hinge is employed, the brace functions to relieve unicompartmental osteoarthritis affecting the lateral condyle (see para. 0027).

Sterling fails to teach that the rotational and off-loading forces are generated by a combination of a first and second hinge, the first hinge located medial to the knee and the second hinge located lateral to the knee, wherein said first hinge has a first variable center of rotation and said second hinge has a second variable center of rotation.

Turrini et al., however, discloses a brace for an osteoarthritic knee comprising both lateral and medial hinges which supports both the lateral and medial sides of an osteoarthritic knee

Applicant should not that it has been held that when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common senses. In that instance the fact that a combination was obvious to try might show it obvious under 35 USC 103. *KSR Int'l Co. v. Teleflex, Inc.* 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007). In light of the use of both lateral and medial hinges as demonstrated by Turrini et al., and in light of the disclosure of Sterling, it would have been obvious to one having ordinary skill in the art to try to employ both the medial and lateral hinges on the knee to relieve both medial and lateral unicompartmental osteoarthritis.

As regards claim 18, the knee discussed in Sterling is an osteoarthritic knee (para. 0026).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-

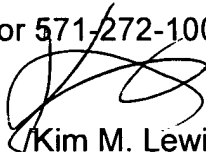
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4796. The examiner can normally be reached on Wednesday to Friday, from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kim M. Lewis/
Kim M. Lewis
Primary Examiner
Art Unit 3772

kml
January 21, 2008